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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BILLINGS DIVISION

ESTATE OF EDWARD R.
CHAMPION, by and through Debbie
Cellan, individually and as Personal
Representative,

Plaintiff,

v.

BILLINGS SKILLED NURSING
FACILITY, LLC D/B/A AVANTARA
OF BILLINGS; LEGACY
HEALTHCARE FINANCIAL
SERVICES, LLC; CASCADE
CAPITAL GROUP, LLC; SHAWNA
JOHNSON; and JOHN DOES 1-25,

Defendants.

Case No.

NOTICE OF REMOVAL

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Ex.	Document
A	Amended Complaint and Jury Demand
B	Complaint and Jury Demand other pleadings filed in District Court
C	Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act April 17, 2020, as Modified on May 19, 2020
D	Letter from Office General Counsel for Dept of Health and Human Services and Guidance dated August 31, 2020
E	Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act October 22, 2020, as Modified on October 23, 2020
F	Notice of Filing Statement of Interest of the United States and Statement of Interest of the United States

Defendants Billings Skilled Nursing Facility, LLC D/B/A Avantara of Billings (“Avantara”), Legacy Healthcare Financial Services, LLC, and Cascade Capital Group, LLC (collectively “Defendants”),¹ through counsel, remove this case from the Montana Thirteenth Judicial District Court, Yellowstone County, to the United States District Court for the District of Montana pursuant to 28 U.S.C. §§ 1331, 1441, 1442 and 1446, the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e (2005) (the “PREP Act”), and the Declaration for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198-07 (March 17, 2020) (including all amendments thereto).

This case is removable because federal question jurisdiction exists by virtue of complete preemption under the PREP Act and pursuant to the *Grable* doctrine. In addition, federal question jurisdiction exists under the federal officer removal statute, 28 USC § 1442.

PROCEDURAL HISTORY

1. On June 16, 2021, Plaintiff filed an Amended Complaint in the Montana Thirteenth Judicial District Court, Yellowstone County, DV-21-0134. A true and accurate copy of Plaintiff’s Amended Complaint is attached hereto. (Exhibit A.)

¹ The use of the word “Defendants” does not refer to Shawna Johnson or any John Doe defendants.

2. Defendants' removal is timely under 28 U.S.C. § 1446(b) as it is being filed within 30 days of service of the Complaint on July 19, 2021.

3. In accordance with 28 U.S.C. § 1446(a), a true and accurate copy of all of the process and pleadings filed in the action to date, along with a copy of the civil docket sheet, are collectively attached. (Exhibits A & B.)

4. This Notice of Removal is being filed in the United States District Court for the District of Montana, which is the District Court of the United States within which the Montana Thirteenth Judicial District, Yellowstone County action is pending. 28 U.S.C. §§ 1441(a) and 1446(a).

5. Defendants have satisfied all procedural requirements governing removal pursuant to 28 U.S.C. §§ 1441 and 1446, the Federal Rules of Civil Procedure, and the Local Rules of the Court.

6. By filing this Notice of Removal, Defendants do not waive any defenses that may be available to them under state or federal law, including the right to compel arbitration.

PLAINTIFF'S ALLEGATIONS

7. Plaintiff's Complaint alleges, *inter alia*, that Defendants failed to properly monitor, test, and treat Champion for COVID-19 in violation of Montana law and federal Public Health Service regulations, *see generally* 42 C.F.R. Chapter

I, the same regulations that make the PREP Act applicable to the COVID-19 pandemic. *See* 42 C.F.R. §§ 110.1 to 110.100; 42 C.F.R. Ch. I, Subch. J, Pt. 110. Because of their alleged negligence, the Estate claims Champion wrongfully died—though Plaintiff does not allege outright that Champion died from COVID-19, that is the clear logical impact of the First Amended Complaint. (Ex. A, ¶¶ 53–108).

8. Plaintiff’s cause of action against Defendants includes counts titled Negligent Care, Negligent Management, Negligence Per Se (based on alleged violations of Montana Law and federal Public Health Service regulations), Negligent Misrepresentation, violation of the Montana Consumer Protection Act, Wrongful Death, Unjust Enrichment, and Conspiracy. (Ex. A, ¶¶ 53–108).

9. Plaintiff’s survivorship, wrongful death, and all other claims arise from Defendants’ response to the COVID-19 pandemic and their decision-making concerning COVID-19 testing, COVID-19 monitoring, and COVID-19 infection control measures. In particular, Plaintiff takes issue with Defendants’ purportedly: improper use and administration of countermeasures to monitor temperature, respiratory rate, pulse, oxygen saturation, vital signs and blood pressure; improper use and administration of oxygen to decedent; and improper administration of their countermeasure program aimed towards preventing and mitigating the spread of

COVID-19 at the facility—all of which are alleged to have resulted in Plaintiff’s death due to complications from Covid-19.

I. Federal Question Jurisdiction Exists Under 28 USC § 1331 By Virtue Of Complete Preemption Under The PREP Act.

10. This case is removable under 28 U.S.C. § 1441(a) on the basis of “original jurisdiction.” Plaintiff’s Complaint asserts claims “arising under” federal law within the meaning of § 1331, as Plaintiff’s allegations invoke the exclusive federal jurisdiction of the Court by way of the complete preemptive force of the PREP Act. *See* 42 U.S.C. § 247d-6d(e) (providing an exclusive federal cause of action and exclusive federal jurisdiction for claims arising from the alleged administration and use of COVID-19 countermeasures); *see also* 42 U.S.C. § 247d-6d(a)(1), (b)(8) (providing immunity from suit and liability under state and federal law, and preemption of state law).

A. The PREP Act Provides for Complete Preemption

11. “When [a] federal statute completely preempts [a] state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law.” *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003). *Beneficial* provides that state claims may be removed to federal court in two circumstances: (1) when a federal statute wholly displaces the state-law cause of action; or (2) when Congress expressly provides. *Id.* Both circumstances apply here. The PREP Act wholly displaces state

law causes of action for claims related to a covered person’s use, misuse, nonuse, allocation, or administration of countermeasures to combat a pandemic by creating an exclusive federal remedy for those claims involving both an administrative and judicial component. 42 U.S.C. §§ 247d-6e, 247d-6d(d)(e). This federal remedial structure was purposefully established by Congress, and it is explicitly “exclusive of any other civil action or proceeding for any claim or suit [the PREP Act] encompasses” 42 U.S.C. § 247d-6e(d).

i. The PREP Act is Made Applicable to the COVID-19 Pandemic.

12. The PREP Act, which is part of the Public Health Services Act (“PHSA”), 42 U.S.C. § 201, *et seq.*, grants healthcare providers and other covered persons immunity from claims for injuries related to the use of approved countermeasures to combat a national public health emergency, such as the COVID-19 pandemic. Congress’s goal was to enable healthcare providers, including nursing facilities, to focus on using every available means to combat a public health emergency and save lives without being chilled in their efforts by the threat of lawsuits. 42 U.S.C. § 247d-6d.

13. The PREP Act is triggered when the Secretary of the Department of Health and Human Services (“HHS”) issues a “declaration” defining the scope and breadth of PREP Act protections relevant to a particular public health emergency. *See* 42 U.S.C. § 247d. The PREP Act provides that when a “disease or other health

condition or other threat to health constitutes a public health emergency,” the Secretary of HHS may issue a declaration “recommending[] . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures” against the disease. *Id.*

14. Notably, Congress also precluded any judicial review of the Secretary’s actions under the PREP Act giving his decisions and proclamations the force of law: “[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.” 42 U.S.C. 247d-6d(b)(7).

15. When the Secretary issues a declaration invoking the PREP Act for a specific public health crisis “covered persons” who administer or use “covered countermeasures” “**shall be** immune from suit and liability under Federal and State law with respect to **all** claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” as defined by the Secretary of HHS. 42 U.S.C. § 247d-6d(a)(1) (emphasis added).

16. A “covered person” includes a person or entity that “is a qualified person” or a “program planner”. 42 U.S.C. § 247d–6d(i)(2)(B). A “qualified person” is defined as a “licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the

law of the State in which the countermeasure was prescribed, administered, or dispensed.” 42 U.S.C. § 247d–6d(i)(2)(B)(iv). A “program planner” is defined as

[A] State or local government, including . . . a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

42 U.S.C. § 247d– 6d(i)(6). Further, the PREP Act defines a “person” as “an individual, partnership, corporation, association, entity, or public or private corporation.” 42 U.S.C. § 247d–6d(i)(5).

17. Congress provides two exclusive federal remedies in the PREP Act for individuals with claims for loss arising out of the use or administration of covered countermeasures. First, the Act creates a “Covered Countermeasure Process Fund” for purposes of “providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” 42 U.S.C. § 247d-6e(a). This pre-litigation administrative remedy is subject to judicial review under the Administrative Procedure Act, 5 U.S.C. §§701, *et. seq.*

18. Second, an injured person may bring “an exclusive Federal cause of action” under the PREP Act “against a covered person for death or serious physical

injury proximately caused by willful misconduct.” 42 U.S.C. § 247d-6d(d)(1).

Significantly, the PREP Act sets forth specific and comprehensive procedures that govern the federal lawsuit asserting this cause of action. 42 U.S.C. § 247d-6d(e).

19. In addition, Congress expressly wrote preemption into the PREP Act, stating that “no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under this section” and relates to, among other things, use or administration of the covered countermeasure. 42 U.S.C. § 247d-6d(b)(8)(A)-(B).

20. In accordance with Congressional authority, at the start of the pandemic, the Secretary of HHS invoked the PREP Act to cover COVID-19 by issuing a declaration on March 17, 2020, announcing that, as of February 4, 2020, “[l]iability immunity as prescribed in the PREP Act. . . is in effect” for any “[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency” related to COVID-19. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198, 15201-02 (Mar. 17, 2020), amended by 85 Fed. Reg. 21012 (Apr. 15, 2020) (the “Declaration”).

21. In that Declaration, the term “administration” is defined to extend beyond the physical distribution of COVID-19 countermeasures to the “activities and decisions directly relating to public and private delivery distribution and dispensing of the countermeasures to recipients,” and to the “management and operation of countermeasure programs” as well as the “management and operation of locations for [the] purpose of distributing and dispensing countermeasures.” See 85 Fed. Reg. 15202.

22. The Declaration also broadly defines “covered countermeasure” as:

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product. Covered Countermeasures must be “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

85 Fed. Reg. 15198.

23. The Declaration was subsequently amended to add respiratory protective devices to the list of covered countermeasures. See 85 Fed. Reg. 21012, 21013.² On June 8, 2020, the Declaration was amended again to reflect HHS’s

² The Secretary issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include

initial intent to “identify the full range of qualified countermeasures” as permitted under the PREP Act. 85 Fed. Reg. 35100, 35101.

24. HHS also issued an Advisory Opinion regarding the Declaration on April 17, 2020, recognizing its broad, preemptive nature. (Exhibit C.) The Opinion states that “immunity covers claims for loss sounding in tort or contract”, and that “PREP Act immunity must be read in light of the PREP Act’s broad, express-preemption provision.” (Ex. C at 2.)

25. On August 14 and August 31, 2020, additional guidance was issued by HHS that: (a) unequivocally confirm that senior living communities, such as Defendant Avantara, are “covered persons” that may be immunized under the PREP Act by virtue of their status as both “program planners” and “qualified persons”; and (b) verify that COVID testing in nursing homes are a covered countermeasure triggering the Act. (Exhibit D.)

26. On October 23, 2020, HHS issued “Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and Secretary’s Declaration Under the Act,” confirming that “administration” under the PREP Act is much broader than the mere physical provision of a countermeasure to a recipient and encompasses activities related to the “management and operation” of COVID-19 countermeasure programs and those facilities that provide countermeasures to

qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. See 85 FR 21012.

recipients. (Exhibit E.) This Advisory Opinion flatly rejects as “wrong” a pre-pandemic New York trial court ruling in *Casabianca v. Mt. Sinai Medical Center*, 2014 WL 10413521 (New York Co. Dec. 12, 2014), that the PREP Act requires the “direct physical” administration of a COVID-19 countermeasure and that the Act is not applicable to claims involving an omission or failure to act.

27. Further, on December 3, 2020, the HHS Secretary issued the Fourth Amendment to the Declaration (“Amendment Four”) (published at 85 Fed. Reg. 79190 (Dec. 9, 2020)), which:

- (a) Expressly adopts all COVID-19 Advisory Opinions into its initiating Declaration, giving those directives controlling authority over interpretations of the PREP Act; 85 Fed. Reg. 79190, 79191, 79192, 79194-95;
- (b) Declares that an omission to administer a covered countermeasure can fall within the PREP Act’s protections; 85 Fed. Reg. 79190, 79191, 79194, 79197; and
- (c) Makes explicit that cases involving COVID-19 covered countermeasures are to be in the federal system as provided by Congress and that this “federal jurisdiction” is essential to the uniform provision of a national response to the COVID-19 pandemic; 85 Fed. Reg. 79190, 79194, 79196, 79197-98.

28. Amendment Four also addresses HHS’s authority to define the application of the PREP Act by stating: “42 U.S.C. 247d-6d(b)(7) provides that ‘[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.’” *See* Amendment Four at 26 n.25.

29. On January 8, 2021, HHS published an Advisory Opinion of the Office of General Counsel addressing questions raised by the Fourth Amendment. *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021) (“AO 21-01”). AO 21-01 confirms the Secretary’s previous proclamations, stating that the PREP Act is indeed invoked by allegations that include not only “use” or administration of countermeasures, but alleged failure to act or inaction, where the non-use was the result of conscious decision-making. *See, e.g., Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, No. 1:21-cv-00334 (W.D. La. Apr. 30, 2021), *12 (concluding that “HHS’s interpretation of the PREP Act and its scope [as set forth in AO 21-01] is reasonable” and, moreover, warrants deference given: “(i) the PREP Act’s broad grant of authority to the HHS Secretary; (ii) the Secretary’s express incorporation of the OGC’s Advisory Opinions into the Declarations for purposes of construing the PREP Act; (iii) the complexity of the relevant statutory provisions; (iv) the technical nature of the subject matter; and (v) the need for uniformity in the judiciary’s interpretation of the PREP Act across the United States.”).

30. AO 21-01 also states that “[t]he PREP Act is a ‘Complete Preemption’ Statute,” because it establishes both a federal and administrative cause of action as the only viable claim and vests exclusive jurisdiction in federal court.

ii. *The New Administration and Federal Courts Reaffirm the PREP Act Provides Complete Preemption.*

31. Consistently, in 2021, the new Administration reaffirmed that the PREP Act provides for complete preemption of COVID-19 state law claims. On January 28, 2021, HHS amended the Declaration for the fifth time, again asserting that HHS Advisory Opinions are incorporated into the original Declaration. *See* Fifth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, (Jan. 28, 2021), 86 Fed. Reg. 7872, 7874 (stating “[t]he plain language of the PREP Act makes clear that there is complete preemption of state law.”); *see also* U.S. Dep’t of Health & Human Services, *Renewal of Determination That A Public Health Emergency Exists* (July 19, 2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-19July2021.aspx> (last accessed Aug. 5, 2021).

32. Two additional amendments further confirm the preemptive effect of the PREP Act, with the sixth on February 16, 2021 and the seventh on March 16, 2021.

33. Given the congressional delegation of authority to the Secretary and the Congressional dictate precluding any judicial review of the Secretary’s actions under the PREP Act, the Declaration – including all amendments thereto as well as the Advisory Opinions incorporated therein by the Secretary – has controlling

force of law. Also, HHS’s interpretive proclamations regarding the PREP Act are alternatively entitled to *Chevron* controlling deference. *See Chevron, Inc. v. NRDC, Inc.*, 467 U.S. 837, 843-44 (1984).

34. In addition to these controlling HHS authorities, the U.S. Department of Justice (“DOJ”) filed a Statement of Interest (“SOI”) of the United States in *Bolton v. Gallatin Center for Rehabilitation & Healing, LLC*, No. 3:30-cv-00683 (M.D. Tenn. Jan. 19, 2021) (DN 35), which constitutes the official position of the United States’ interest in the enforcement of the PREP Act, stating that the PREP Act “completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency.” (Exhibit F at 1, 7-8.) Further, it states that the two key provisions of the PREP Act – the immunity provision for all Federal and state law claims, and the exclusive alternative federal remedy provision, established as the sole exception to immunity – operate together to demonstrate the PREP Act’s completely preemptive nature. *Id.* at 7–8. The DOJ also noted that the PREP Act is crucial to the “whole-of-nation response” to public health emergencies (which depends on cooperation among private-sector partners and state and local officials across the nation), and “sweeping” immunity was granted to encourage such cooperation. *Id.* at 1-2.

35. On February 10, 2021, the U.S. District Court for the Central District of California relied HHS controlling authority in denying a motion for remand in

an action against a nursing home which alleged failure to adequately use PPE and other COVID countermeasures, holding that “because the OGC stated that the PREP Act is a complete preemption statute . . . an adequate basis for federal question jurisdiction exists.” *See Garcia v. Welltower OpCo Grp. LLC*, 2021 WL 492581, at *9 (C.D. Cal. Feb. 10, 2021). The Court further found that the allegations of the complaint fell squarely within the scope of the PREP Act:

Plaintiffs’ injuries “aris[e] out of, relat[e] to, or result[] from the administration to or the use by an individual of a covered countermeasure.” *See* 42 U.S.C. § 247d- d(a)(1). For example, the FAC details infection control measures and procedures including symptom checking, staff monitoring and screening, and limiting visitation In other places, the FAC directly draws upon the use (and in some case, misuse) of PPE The FAC also details screening measures employed by [Defendants] related to certain professional services provided within the facility. These allegations of use and misuse of PPE and the infection control measures directly relate to covered countermeasures within the meaning of the PREP Act.

Id. at *8.

36. More recently, the District Court for the Western District of Louisiana likewise agreed that the PREP Act is a complete preemption statute, finding that the PREP Act confers federal jurisdiction and completely preempts claims falling within its scope because it includes: a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; a specific jurisdictional grant to the federal courts for enforcement of the right; and a clear Congressional intent that claims brought under the federal law be exclusive.

See Rachal, Civil Docket No. 1:21-CV-00334, *3 n.3. Also, in two other cases, courts have recently conceded jurisdiction and the applicability of the PREP Act where other senior living facilities have moved to dismiss claims based on the immunity and other protections provided therein. *See Reilly v. Delta Healthcare II, LLC*, No: 8:21-cv-1013-JSM-JSS (M.D. Fla. June 7, 2021); *Branch v. Lilac Holdings, LLC*, No. 21-cv-00605-BAS-MDD (S.D. Cal. June 16, 2021).

iii. *Under the Analysis in Beneficial, Congress Explicitly Provided for Complete Preemption in the PREP Act.*

37. Congress intended to regulate national responses to pandemics and other public health emergencies by making the PREP Act a complete preemption statute. The PREP Act expressly satisfies the *Beneficial* test for complete preemption in stating that “a covered person **shall** be immune from suit and liability under Federal and State law with respect to **all** claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.” 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The PREP Act further provides that this immunity “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure . . . or use of such countermeasure.” 42 U.S.C. § 247d-6d(a)(2)(B).

38. Significantly, the PREP Act also provides an extensive exclusive federal administrative and litigation process for COVID-19 claimants in accordance the directives of *Beneficial* by providing for federal redress and displacing state-law liability. Specifically, the PREP Act establishes a pre-litigation no-fault monetary fund for those injured by the use or administration of covered countermeasures that must be exhausted prior to relief under the federal civil litigation process (42 U.S.C. § 247d-6e(a), (d)(1)), requiring an exclusive federal remedy for all claims related to countermeasures (42 U.S.C. § 247d-6e(d)(5)), and providing a Federal cause of action for willful misconduct claims as the single exception to immunity (42 U.S.C. § 247d-6d(d)(1)).

39. In addition, Congress expressly preempts all state law claims. *See* 42 U.S.C. § 247d-6d(b)(8).

40. HHS has instructed time and again that this preemption is to be given the broadest possible application.³

B. Plaintiff's Claims Fall Within the Purview of the PREP Act.

41. Here, based on the face of the Complaint, the totality of the allegations made therein and the logical impact of its most central allegations, the PREP Act is implicated by Plaintiff's claims against Defendants as "covered

³ HHS refers eight times to the broad applicability of preemption of state law claims. *See* Advisory Opinion 21-01 (Jan. 8, 2021) at 1, Advisory Opinion 20-04 (Oct. 23, 2020), Advisory Opinion 20-02 (May 19, 2020) at 4-5, Advisory Opinion 20-01 (Jan. 8, 2020) at 2. Also, HHS refers six times to the broad applicability of immunity from state law claims. *See* Advisory Opinion 20-04 (Oct. 23, 2020) at 1-2, and Advisory Opinion 20-01 (Jan. 8, 2020) at 2, 4, 7.

persons” engaged in the use and administration -- including the allegedly improper use and administration -- of “covered countermeasures” under the Act. 42 U.S.C. § 247d–6d(a)(1). *See Rachal v. Natchitoches Nursing & Rehab Center LLC*, Civil Docket No. 1:21-CV-00334, *3 n.3 (W.D. La. April 30, 2021); *Garcia*, 2021 WL 492581, at *7 (C.D. Cal. Feb. 10, 2021); *see Reilly*, No: 8:21-cv-1013-JSM-JSS (M.D. Fla. June 7, 2021); *Branch*, No. 21-cv-00605-BAS-MDD (S.D. Cal. June 16, 2021).

42. Again, the PREP Act applies to “covered persons” who administer or use “covered countermeasures,” and thus become “immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1).

43. The Defendants are “covered persons” as contemplated by 42 U.S.C. § 247d–6d and as confirmed by the August 14, 2020 HHS Advisory Opinion in that they are “qualified persons” and “program planners” under 42 U.S.C. § 247d-6d(i)(2)(B); *see supra* Section I.A.i. Defendants were acting as “qualified persons” because they are licensed healthcare providers and administrators authorized to administer and/or use FDA approved medical devices to prevent or mitigate the spread of COVID-19. 42 U.S.C. § 247d-6d(i)(8). Defendants were also acting as “program planners” in that they managed, supervised, and administered infection

control covered countermeasures, including, but not limited to, the use of PPE, pulse oximeters, thermometers, oxygen, visitation restrictions, COVID-19 symptom monitoring, COVID-19 treatment, infection control procedures, screening requirements at the facility in an effort to prevent and mitigate the spread of COVID-19 to its residents during the pandemic. *See, e.g., Rachal*, Civil Docket No. 1:21-CV-0334, *9-10 (finding nursing homes are “covered persons” under the PREP Act); *see supra* Argument Section I.A.i.

44. The Defendants, as covered persons, administered and used “covered countermeasures” under the PREP Act. 42 U.S.C. § 247d-6d(a)(1). As stated in Section I.A.i., covered countermeasures include: antivirals; diagnostic devices; any devices used to treat, diagnose, prevent, or mitigate COVID-19; and respiratory protective devices. In Avantara, while Mr. Champion was a resident, masks were worn, diagnostic devices to test oxygen levels and other vital signs were used, oxygen was provided to treat COVID-19, and social distancing and quarantine plans were made to mitigate the effects of COVID-19.

45. Plaintiff’s claim for loss “aris[es] out of, relat[es] to, or result[s] from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). Specifically, Plaintiff’s claims against Defendants arise from and relate to the manner in which they used, administered, and allocated COVID-19 countermeasures. Plaintiff alleges that Defendants were negligent in

their COVID-19 infection testing and control measures including their use and administration of oxygen and their testing of temperature, respiratory rate, pulse, oxygen saturation, vital signs and blood pressure. Plaintiff also alleges that the facility was understaffed, which relates to Defendants' operation and management and decision-making of their COVID-19 countermeasure program intended to prevent or mitigate the spread of COVID-19 at the facility.

46. Plaintiff alleges that Champion died, and it alleges that his death immediately followed alleged mistreatment for his COVID-19 infection. Plaintiff also alleges that Defendants negligently operated and managed the COVID-19 countermeasure plan, and that the alleged negligent operation and management of their COVID-19 countermeasure facility included social distancing, COVID-19 testing, and patient monitoring for COVID-19 symptoms. These allegations cause this action to fall squarely under the definition of use and "administration" thereby invoking the protections under the PREP Act.

47. Further, Plaintiff specifically contends that Defendants' conduct was negligence per se based on alleged violations of federal Public Health Service regulations—the same regulations that make the PREP Act applicable to the COVID-19 pandemic. *See* 42 C.F.R. §§ 110.1 to 110.100.

48. The claims included within Plaintiff's Complaint are therefore completely preempted under the PREP Act.

II. Federal Question Jurisdiction Also Exists Pursuant to the *Grable* Doctrine.

49. Federal jurisdiction also exists where an action “arises under” federal law and raises a substantial federal issue, actually disputed and substantial. *See Grable & Sons Metal Prods. v. Darue Eng’g & Mfg.*, 545 U.S. 308 (2005). Here, the Complaint raises substantial and disputed issues of federal law related to the Declaration issued under the PREP Act and Defendants’ actions in response to the global COVID-19 pandemic.

50. HHS, by and through its Fourth Amended Declaration and AO 21-01, confirms that the PREP Act confers a separate, independent grounds for federal question jurisdiction under the *Grable* doctrine, stating that “ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court.” AO 21-01 at 5. HHS provides that “there are substantial federal legal and policy . . . interests within the meaning of [the *Grable* doctrine] in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities.” AO 21-01 at 5 (quoting 85 Fed. Reg. at 79, 197).

51. Further, “Congress delegated to [the Secretary] the authority to strike the appropriate Federal-state balance with respect to particular covered countermeasures through PREP Act declarations.” HHS’s interpretation of *Grable* is consistent with the Supreme Court’s long-standing rule “that in certain cases

federal question jurisdiction will lie over state law claims that implicate federal issues.” *Grable*, 545 U.S. at 312.

52. The *Grable* Court determined that there is no single test for determining whether an embedded federal issue exists, but that, in general, a two-step process determines whether a state law claim “arises under” federal law: (1) the state law claim must necessarily raise a stated federal issue that is actually disputed and substantial; and (2) federal courts must be able to entertain the state law claims “without disturbing a congressionally approved balance of state and federal judicial responsibilities.” *Id.* at 314; *see Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804, 808 (1986).

53. Here, both prongs of *Grable* are satisfied. First, Plaintiff brings claims relating to Defendants’ alleged use or administration (or misuse, nonuse, or non-administration) of covered countermeasures in connection with the care and treatment of Champion, which necessarily implicates disputed and substantial federal issues. *See* 42 U.S.C. § 247d-6d.

54. Second, as confirmed by AO 21-01 and the HHS Declaration (and its amendments), the PREP Act expresses a clear intention to supersede and preempt state control of the very issues raised by Plaintiff, i.e., issues concerning Defendants’ conscious decisions as when and how to use or administer covered countermeasures related to COVID-19 infection control.

55. A substantial and disputed federal issue regarding the application of the PREP Act to Plaintiff's claims therefore necessarily exists and must be resolved by this Court to ensure the uniform and appropriate application of the PREP Act. The federal legal and policy issues described in the Fourth Amended Declaration and the HHS Advisory Opinions control and authorize this Court to retain this action under *Grable*.

56. Moreover, the Complaint implicates federal imperatives of the highest and broadest importance: coordination of national disaster relief and the maintenance of infrastructure “essential to the national defense.” *See McMahon v. Presidential Airways, Inc.*, 410 F.Supp.2d 1189, 120-02 (M.D. Fla. 2006) (holding that “the federal issues [were] quite substantial” where national defense is implicated). The “validity of [Plaintiff’s] claims would require that conduct subject to an extensive federal ... scheme is in fact subject to implicit restraints that are created by state law.” *Bd. of Comm’rs v. Tenn. Gas Pipeline Co.*, 850 F.3d 714, 724 (5th Cir. 2017). The “implications for the federal regulatory scheme” of such liability—particularly where the federal scheme relates to critical infrastructure during a national emergency—“would be significant.” *Id.*; *see Xitronix Corp. v. KLA-Tencor Corp.*, 916 F.3d 429, 441 (5th Cir. 2019) (noting that the substantiality requirement is satisfied where a case “put[s] the legality of a federal action in question, in a matter that would have broader ramifications for the legal

system.”). Thus, there is a “serious federal interest in claiming the advantages thought to be inherent in a federal forum” for these claims. *Grable*, 545 U.S. at 313; *see Rose v. SLM Fin. Corp.*, Civ. A. No. 3:05CV445, 2007 WL 674319, at *4 (W.D. N.C. Feb. 28, 2007) (“Where a federal regulatory scheme requires private parties to undertake certain actions in order to comply with the law, the federal courts necessarily have a serious interest in examining the scope of liability that might arise as a result.”). Exercising jurisdiction over Plaintiff’s claims also “would not materially affect, or threaten to affect, the normal currents of litigation” given the “rare” circumstances here.

III. Federal Question Jurisdiction Exists Pursuant to the Federal Officer Removal Statute (28 U.S.C. § 1442(a)(1)).

57. Removal is also proper under 28 U.S.C. § 1442(a)(1), which provides for removal when a defendant is sued for acts undertaken at the direction of a federal officer.

58. There is “a clear command from both Congress and the Supreme Court that when federal officers and their agents are seeking a federal forum, we are to interpret section 1442 broadly in favor of removal.” *Durham v. Lockheed Martin Corp.*, 445 F.3d 1247, 1252 (9th Cir. 2006).

59. This case is removable pursuant to Section 1442(a) because: "(1) Defendant[s] [are] ‘a person’ within the meaning of the statute; (2) Plaintiff’s claims are based upon Defendant[s]’ conduct ‘acting under’ the United States, its

agencies, or its officers as members of the nation's critical infrastructure; (3) Plaintiff's claims are for, or relating to' an act under color of federal office; and (4) Defendant[s] raise a colorable federal defense to the Plaintiff's claims." *Stirling v. Minasian*, 955 F.3d 795 (9th Cir. 2020); *see Fields v. Brown*, No. 6:20-CV-00475, 2021 WL 510620, at *2 (E.D. Tex. Feb. 11, 2021) (holding federal officer removal statute conferred jurisdiction where defendant was "acting under the direction of multiple federal agencies" as part of the federal "critical-infrastructure designation"); *Wazelle v. Tyson Foods, Inc.*, No. 2:20-CV-203Z, 2021 WL 2637335 (N.D. Tex. June 25, 2021).

60. Defendants are "persons" under the federal officer removal statute. Defendants Avantara of Billings, Legacy Healthcare Financial Services, LLC, and Cascade Capital Group, LLC, are all corporate entities, and corporations are "person[s]" pursuant to Section 1442(a)(1). *Fidelitad, Inc. v. Insitu, Inc.*, 904 F.3d 1095, 1099 (9th Cir. 2018) (stating that "corporations are persons under § 1442(a)(1)").

A. Defendants Acted Pursuant to Federal Officer Direction

61. The United States Supreme Court has held that acting pursuant to a federal officer's direction involves "an effort to assist, or help carry out, the duties or tasks of the federal superior." *Watson v. Philip Morris Cos.*, 551 U.S. 142, 152 (2007). The "acting under" requirement is broad and is also to be liberally

construed to cover actions that involve “an effort to assist, or to help carry out, the federal supervisor's duties or tasks.” *Goncalves v. Rady Children's Hosp. San Diego*, 865 F.3d 1237, 1247 (9th Cir. 2017), *quoting Watson*, 551 U.S. 142 (2007). In construing the “acting under” requirement, “courts generally find that persons are ‘acting under’ a federal officer if acts forming the basis of the state suit were performed pursuant to a federal officer’s direct orders or comprehensive and detailed regulations.” *In re Nat'l Sec. Agency Telecommunications Recs. Litig.*, 483 F. Supp. 2d 934, 943 (N.D. Cal. 2007). The “acting under” requirement is met when a defendant is acting pursuant to detailed and ongoing instructions from a federal officer. *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387, 400 (5th Cir. 1998).

62. Defendants acted at all relevant times “to assist, or to help carry out, the duties or tasks of the federal superior,” by aiding the federal government in “fulfill[ing] other basic governmental tasks” that otherwise “the Government itself would have had to perform.” *See Watson*, 551 U.S. at 153-54.

63. More specifically, Avantara was designated as a “critical infrastructure” facility, was closely monitored by the federal government, and assisted the government and, as such, Defendants were “acting under” the direction of a federal officer in responding to COVID-19 pandemic. *Fields v. Brown*, 2021 WL 510620, at *2; *Wazelle v. Tyson Foods, Inc.*, 2021 WL 2637335 (federal court

is the proper forum for this case where defendant was "acting under the direction of multiple federal agencies" as part of the federal "critical-infrastructure designation").

64. Once COVID-19 began to spread, the federal government declared that healthcare providers, including long-term and nursing care facilities were “critical infrastructure” businesses that were obligated to aid the federal government in preventing the spread of the virus during this unprecedented national emergency by following the federal government’s direction under its close supervision.

65. Designating their activities as “critical infrastructure” enabled the federal government to enlist the aid of these private parties to ensure the continued operation of the healthcare infrastructure that is “so vital to the United States that [its] incapacity or destruction . . . would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.” 42 U.S.C. § 5195c(e). And when the federal government instructed these private parties on how to carry on their “critical” business during this national emergency, it enlisted them to carry out duty of the government itself to ensure the continued provision of “services critical to maintaining the national defense, continuity of government, economic prosperity, and quality of life in the United States.” *Id.*; 42 U.S.C. § 5195c(b)(3); *see Wazelle*, 2021 WL 2637335 at *5.

66. Prior to the COVID-19 pandemic, regulation of assisted living facilities was very general in nature. However, as a direct result of the COVID-19 global public health crisis and their designation as critical infrastructure, there was a clear and sudden paradigm shift. Since the pandemic began, through the federal directives issued by the CDC, CMS and others, to them as members of the nation's critical infrastructure by federal authorities have been explicitly guiding operational decisions related to clinical pandemic response in skilled nursing facilities. Facilities were ordered to restrict visitation, cancel communal dining, and implement active screening and staff for fever and respiratory symptoms. Facilities were also instructed on, among other things, which patients and staff to test for COVID-19; under what circumstances to use and how to conserve PPE; when to permit staff who had COVID-19 to return to work; how to mitigate staff shortages including when to permit COVID-19 positive but asymptomatic staff to return to work; maintaining COVID-19 testing protocols; how separately to staff COVID-19 positive and negative residents; and how to handle the isolation of residents infected with COVID-19 and those under investigation for COVID-19. These very detailed clinical directives and instructions represented a marked departure from the regulatory structure which existed before the pandemic.⁴

⁴ E.g., Ctrs. For Disease Control & Prevention, *CDC Health Update and Interim Guidance on the Outbreak of 2019 Novel Coronavirus (2019-n-11 coV)* (Feb. 1, 2020); Ctrs. For Medicare & Medicaid Servs., *COVID-19 Long-Term Care Facility Guidance* (Apr. 2, 2020); Ctrs. For Disease Control & Prevention, *Strategies for Optimizing the Supply of Facemasks* (updated Mar. 17, 2020); Exec. Order No. 20-009; Exec. Order No. 20-52, *Emergency Management-COVID-19 Public Health Emergency*.

67. In a March 20, 2020 memorandum, CMS advised that CMS surveyors would be conducting targeted infection control surveys of providers identified in collaboration with the CDC and the HHS Assistant Secretary for Preparedness and Response to ensure providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic. A skilled facility would be subject to citation and monetary penalties for failure to implement the directives from CMS. Thus, the directives from CMS (which followed and instructed facilities to follow the CDC guidance) were truly mandates, not recommendations. (See CMS Memo QSO 20-20-ALL).

68. The decision in *Fields v. Brown*, No. 6:20-cv-00475, 2021 WL 510620 (E.D. Tex. Feb. 11, 2021) is persuasive. In pertinent part, the court in *Fields* held that a Tyson Foods meatpacking facility was “acting under” the direction of a federal officer because Tyson Foods “exhibited ‘an effort to help assist, or carry out, the duties and tasks’” of the federal government by “working directly with the Department of Agriculture and the [Food Safety and Inspection Service] to guarantee that there was an adequate food supply” during the COVID-19 pandemic.” *Id.* at *3 (citation omitted). In holding that federal officer removal was appropriate, and that the Tyson Foods did in fact “act[] under” the direction of a federal officer in continuing its operations, the court rejected plaintiffs’ argument that Tyson Foods merely “communicated with federal regulators and that Tyson

Foods was subject to federal regulation.” *Id.* Rather, the court relied on the additional facts plead by Tyson as outcome determinative: *inter alia*, “. . .the critical-infrastructure designation. . .” of Tyson Foods’ plant, the fact that the “Department of Agriculture and the [Food Safety Inspection Service] closely monitored Tyson Food’s meatpacking plants, staffing some employees onsite,” and that “Congress even allocated additional funding to to ensure that they had the resources to adequately supervise meatpacking plants like that one at issue. . .” *Id.* <<maybe mention that the Wazelle court agreed, reaching the same conclusion>>

69. Again, Avantara was designated as a “critical infrastructure” facility, was subject to monitoring by the federal government, and assisted the government and, as such, Defendants were “acting under” the direction of a federal officer in responding to COVID-19 pandemic. They were subject to the various detailed rules about staffing, resident management, and COVID-19 testing and monitoring. Thus, like Tyson foods in *Fields* and *Wazelle*, Defendants here were “acting under” the direction of a federal officer because in an effort to help assist, or carry out, the duties and tasks of the federal government.

B. Causal Nexus Exists Between Plaintiff’s Claim and the Actions Taken by Defendants Pursuant to Federal Direction.

70. The next requirement, often referred to as the “nexus” or “causation” requirement, demands that the alleged conduct have been undertaken “for or relating to any act under color of [a federal] office.” 28 U.S.C. § 1442(a)(1). After

statutory amendments in 2011, a case is removable so long as plaintiff's claims are merely "connected" or "associated" with federal directions. *See Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286, 292 (5th Cir. 2020) (en banc) (Congress "broadened federal officer removal to actions, not just *causally* connected, but alternatively *connected* or *associated*, with acts under color of federal office"). The federal officer removal statute no longer imposes a "direct causal nexus" requirement. *See Wazelle*, 2021 WL 2637335, at *5 ("The *Winters* standard [requiring a direct causal nexus] no longer governs."). "[I]t is sufficient for there to be a connection or association between the act in question and the federal office." *In re Commonwealth's Motion to Appoint Couns. Against or Directed to Def. Ass'n of Philadelphia*, 790 F.3d 457, 471 (3d Cir. 2015). Moreover, "[i]n assessing whether a causal nexus exists, [the court] credit[s] the defendant's theory of the case." *Leite*, 749 F.3d at 1124.

71. Here, there is a clear causal nexus between the claims against Defendants and the actions undertaken by them pursuant to federal directives in responding to and administering care related to the COVID-19 outbreak. Plaintiff's Complaint specifically alleges a deficiency in Defendants' actions with regard to infection control procedures, monitoring vital signs, COVID-19 testing, provision of oxygen, and staffing – all of which were all undertaken in responding to constantly evolving federal directives to preserve resources and enable a

nationwide response in an effort to prevent the spread of COVID-19 within this nursing facility. *See Wazelle*, 2021 WL 2637335 at *5.- ("[l]ogically, the choice of what safety precautions should be taken—such as whether personal protective equipment should be provided or what social-distancing measures should be adopted—is connected to the broader decision to keep the plant operating during the pandemic" so as to ensure national stability.

72. Unquestionably, these claims easily satisfy the "minimal 'causal connection'" requirement as evidenced by the nature of the claims and the various orders, guidelines, and recommendations followed by Defendants in responding to the pandemic. *Latiolais*, 951 F.3d at 295 (quoting *Willingham v. Morgan*, 395 U.S. 402, 409 (1969), and *Jefferson Cnty. V. Acker*, 527 U.S. 423, 432-33).

C. Defendants Have a Colorable Defense Based on Federal Law

73. For purposes of removal, Defendants must also present a colorable defense, but the defense need not be "clearly sustainable," as the purpose for the removal statute is to assure that the validity of the defense is tried in federal court. *Willingham v. Morgan*, 395 U.S. 402, 407 (1969). "[O]ne of the most important reasons for removal is to have the validity of the defense of official immunity tried in a federal court;" for this reason, the Supreme Court has "rejected a narrow, grudging" approach when analyzing whether a defendant had raised a colorable federal defense. *Jefferson Cty. v. Acker*, 527 U.S. 423, 431 (1999).

74. Defendants assert a federal defense in this case - namely, immunity under the PREP Act for their administration and use of “covered countermeasures.” In doing so, Defendants satisfy the “colorable federal defense” element of the federal officer removal statute. A defendant need only show it has a plausible federal defense. *Ruppel v. CBS Corp.*, 701 F.3d 1176, 1182 (7th Cir. 2012).

75. Here, Defendants are immunized under the PREP Act for the conduct about which Plaintiff complains as Defendants acted in accordance with federal directives and guidelines aimed to protect residents and staff from COVID-19 exposure and prevent the spread of the virus.

CONCLUSION

76. Accordingly, this case may be properly removed to federal court because federal question jurisdiction exists by virtue of complete preemption under the PREP Act and pursuant to the *Grable* doctrine, and the claims in this case fall within the purview of the PREP Act. In addition, this case is properly before this federal court by virtue of the federal officer removal statute.

///

DATED this 6th day of August, 2021.

BROWNING, KALECZYC, BERRY & HOVEN, P.C.

By /s/Oliver H. Goe

Oliver H. Goe

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LLC

CERTIFICATE OF COMPLIANCE

Pursuant to L.R. 7.1(d)(2)(E), I certify that Notice of Removal, is double spaced, is a proportionately spaced 14 point typeface, and contains 7,660 words.

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of August, 2021, a true copy of the foregoing was served:

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